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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/236,995	01/26/1999	PRAMOD MAHAJAN	5718-34	9734

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/26/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/236,995

Applicant(s)

MAHAJAN ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 16 is acknowledged. The traversal is on the ground(s) that it would not present a serious search burden to examine the claims together. Applicant's argument is noted and found persuasive. Accordingly, claims 1-23 have been examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 8, 12 and 21 recite an antisense sequence for a plant poly ADP-ribose polymerase. The pending claims have been accorded the broadest reasonable interpretation consistent with the specification. See MPEP 2111. Thus, "antisense" molecules encompass mere complimentary sequences and those molecules that specifically inhibit the expression or function of ADP-ribose polymerase. However, the specification fails to provide adequate written

description for the breadth of sequences encompassed by the instant claims. The claims drawn to antisense sequences may encompass any sequence of any length for any plant poly ADP-ribose polymerase. This claim is drawn to a broad genus of antisense sequences such that one of skill in the art could not reasonably conclude that Applicant had possession of the invention claimed. Applicant may show possession by claiming all the limitations of the invention in full, clear and concise terms using descriptive means such as words, structures, figures, diagrams, or formulas. See MPEP 2163 and *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Applicant has failed to provide structures of the antisense sequences claimed nor has Applicant disclosed any relevant examples of antisense molecules. Applicant has also failed to describe a correlation between the antisense sequences encompassed by the breadth of the instant claims and their function.

A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. See MPEP 2163

Although Applicant claims an antisense sequence to plant poly ADP-ribose polymerase and SEQ ID NO:1, Applicant has not shown any antisense sequences which would modulate the activity of the polymerase in the cell. Applicant has merely shown how to find the antisense sequence. Applicant has not shown "sufficient identifying characteristics" to support the instant limitation for written description purposes.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "chimeric gene" refers not only to a coding sequence but also to an entire genomic structure including introns and all regulatory regions upstream and downstream of coding sequences. Since the entire genomic structure of a representative number of eukaryotic genes is not known, these claims are subject to a rejection for an inadequate written description. It is suggested that the word gene be replaced with terminology such as "nucleic acid sequence."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12 and 21 recite the limitation that the claimed nucleic acid molecule hybridizes under "stringent hybridization conditions." Without clarification, the term, "stringent hybridization conditions," remains unclear. Stringent hybridization conditions rely on variable factors such as the length of the nucleotide, GC content, salt conditions, temperature *etc.* Therefore, specific guidance is required in the claim, itself, or the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession No.

AJ222589 (Babiyachuk et al. 19 Noveber 1997).

The invention of the instant claims is drawn to SEQ ID NOs: 1, SEQ IDNO: 2, SEQ ID NO: 3 or the C terminal domain of SEQ ID NO: 4.

Accession No. AJ222589 discloses a sequence with 100 percent identity with SEQ ID NO:4, 100 percent identity with SEQ ID NO:3, 95 percent identity with SEQ ID NO:2 and 97 percent identity with SEQ ID NO:1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession No:AJ222589 as applied to claims 1 above, and further in view of DeBlock (WO 97/06267).

The invention of the instant claims is drawn to a chimeric nucleic acid construct comprising the sequences of SEQ ID Nos:1, 2, 3, or 4, an antisense sequence of SEQ ID NO:1 or the C terminal domain of SEQ ID NO:4 with a heterolous promoter. A plant cell is transformed with this construct.

Accession No: AJ222589 is relied upon as described above. The instant reference fails to disclose a chimeric construct, transformed plant cells or method of transforming plants cells.

De Block discloses a construct comprising a heterologous tissue specific promoter and an inhibitor of plant poly ADP-ribose polymerase that is transformed into both monocotyledonous and dicotyledonous plants. See abstract, pages 1-3 and page 61.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to create vector construct comprising a heterologous promoter and a sequence of SEQ ID Nos: 1, 2, 3 or 4 encoding a plant poly ADP-ribose polymerase in order to modulate expression of the polymerase and control the metabolism of the plant. De Block teaches a method and construct wherein an inhibitor of plant poly ADP-ribose polymerase is transferred to a cell such that the expression of the polymerase is inhibited and the metabolism of the plant is controlled by a tissue specific promoter. The ordinary skilled artisan would have been motivated by the disclosure of De Block to use the plant poly ADP-ribose polymerase disclosed in Accession No: AJ222589 to modulate plant metabolism. Moreover, it is well within the purview of the ordinary skilled artisan to create novel constructs and transform them into cells such that the ordinary skilled artisan would have a reasonable expectation of success of transforming a cell with a construct comprising plant poly ADP-ribose polymerase. Therefore, absent evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves, J.D. whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves, J.D.
March 25, 2002


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